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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/787,327  | 04/20/2001  | Nathaniel A. Brown   | PU3514USW           | 9628             |
| 23347   | 7590        | 03/12/2002           |                     | EXAMINER         |
| DAVID J LEVY, CORPORATE INTELLECTUAL PROPERTY<br>GLAXOSMITHKLINE<br>FIVE MOORE DR.<br>PO BOX 13398<br>DURHAM, NC 27709-3398 |             |                      | JIANG, SHAOJIA A    |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1617                | 1                |
| DATE MAILED: 03/12/2002   |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 09/787,327             | BROWN ET AL.        |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Shaojia A. Jiang       | 1617                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 04 January 2002.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,2,4-10,12-15,22 and 23 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1,2,4-10,12-15,22 and 23 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

|  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

### **DETAILED ACTION**

This Office Action is a response to Applicant's amendment and response filed on January 4, 2002 in Paper No. 8 wherein claim 10 has been amended and claim 23 is newly submitted, and claim 3 is cancelled. Currently, claims 1-2, 4-10, 12-15, and 22-23 are pending in this application.

Applicant's remarks filed on January 4, 2002 in Paper No. 8 with respect to the objection to the specification for the incorporation of a foreign patent in the specification of record stated in the Office Action dated July 31, 2001 have been fully considered and are found persuasive. Therefore, this objection is withdrawn.

Applicant's amendment (amending claim 10) filed on January 4, 2002 in Paper No. 8 with respect to the rejection of claims 10 and 12-15 made under 35 U.S.C. 112 second paragraph for the expression of a broad range or limitation together with a narrow range, of record stated in the Office Action dated July 31, 2001 has been fully considered and found persuasive to remove the rejection since the said expression has been deleted from the claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4-10, 12-15, and 22-23 1-10, 12-15, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korba and Glazier et al. (5,627,165) essentially for reasons of record stated in the Office Action dated July 31, 2001.

Applicant's remarks filed on January 4, 2002 in Paper No. 8 with respect to the rejection of claims 1-10, 12-15, and 22 made under 35 U.S.C. 103(a) as being unpatentable over Korba and Glazier et al. of record stated in the previous Office Action (July 31, 2001) have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Applicant's assertion that none of the cited references specifically teaches the combination herein has been considered but is not found persuasive. It has been held that it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for same purpose in order to form a third composition that is to be used for the very same purpose; idea of combining them flows logically from their having been individually taught in prior art. *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980. See MPEP 2144.06. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. *In re Keller*, 642 F.2d 413, 208 SPQ 871 (CCPA 1981); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145. In the instant case, as discussed in the set forth 103(a) rejection in the previous Office Action, both lamivudine and adefovir or adefovir dipivoxil are known to be useful in a pharmaceutical composition or formulation and in methods of treatment HBV infections based on the combined teachings of the

cited references. Moreover, a combination of lamivudine and other antiviral agents is known to be useful in the treatment of HBV according to Korba. Hence, adefovir is considered to be the other antiviral agent. Therefore, one of ordinary skill in the art would have reasonably expected that combining lamivudine and adefovir or adefovir dipivoxil known useful for the same purpose in a composition to be administered would improve the therapeutic effect for treating HBV infections, absent evidence to the contrary.

Applicant's assertion that Figure 1 of the specification demonstrates the claimed combination herein shows unexpected and synergistic activity against HBV production has been considered but is not found convincing since the data in Figure 1 herein is unclear as to how the graphical presentation herein may be taken to demonstrate unexpected and synergistic effect in the instant invention. Moreover, the clear explanation of pointing out exactly what facts are established therein and relied upon by applicant is not seen in the specification (see page 20). Applicant has the burden to explain the experimental evidence. See *In re Borkowski and Van Venrooy* 184 USPQ 29 (CCPA 1974). Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

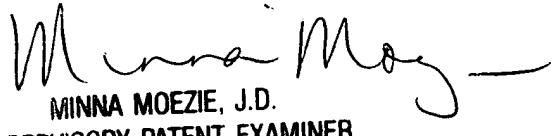
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.  
Patent Examiner, AU 1617  
March 8, 2002



MINNA MOEZIE, J.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600